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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,605	09/12/2001	Robert Ian Lechler	5585-59112	2755

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1642	7

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/868,605	Lechler et al
Examiner	**Art Unit**
Canella	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 8, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above, claim(s) *3-5* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1, 2, and 6-26* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Claims 1-26 are pending in the application and are currently under prosecution. It is noted that claims 3-5 are so indefinite that at this time they cannot be included in any group because they are all dependent upon claim 1, all recite the phrase "said peptide" wherein the term "peptide" is not found in claim 1. Upon amendment of the claims, Claims 3-5 will be rejoined to the appropriate Group. Rejoinder of the claims may result in additional restriction of the claims.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13:

Group I, claims 1, 2-in-part drawn to CD40, 6, 7, 8, 9-in-part drawn to CD40, claim 10-in-part if amended to recite "B-cell epitope" rather than "B-cell", 14, 15, 24, 25 drawn to a method of improving tolerance to a xenograft comprising immunizing a mammal with an immunogen comprising at least one T-cell epitope and at least one porcine polypeptide B-cell epitope wherein the B-cell epitope is a peptide derived from porcine CD40 and the T-cell epitope comprises a tetanus toxoid polypeptide, and a composition comprising at least one T-cell epitope and at

least one porcine polypeptide B-cell epitope wherein the B-cell epitope is a peptide derived from porcine CD40, wherein said peptide is the first underlined peptide disclosed in Figure 22 and the T-cell epitope comprises a tetanus toxoid polypeptide.

Groups 2-479,996,686, claims 1, 2-in-part drawn to at least one B-cell epitope derived from the group consisting of CD40, CD80, CD86 and VCAM (wherein CD40 alone is not included), 6, 7, 8, 9-in-part drawn to B-cell epitopes, claim 10 if amended to recite "B-cell epitope" rather than "B-cell", 11-in-part, 12-in-part (It is noted that claims 10-12 are drawn to B-cell epitopes which comprises at least one peptide as represented in Figures 22, 24, 26, respectively wherein the first underlined peptide disclosed in Figure 22 is not included), 13-15, 24-25 drawn to a method of improving tolerance to a xenograft comprising immunizing a mammal with an immunogen comprising at least one T-cell epitope and at least one porcine polypeptide B-cell epitope and the T-cell epitope comprises a tetanus toxoid polypeptide, and a composition comprising at least one T-cell epitope and at least one porcine polypeptide B-cell epitope. It is noted that claim 2 is drawn to four different B-cell-type epitopes, claim 10 is drawn to 7 different underlined peptides represented in Figure 22, Claim 11 is drawn to 12 different underlined peptides represented in Figure 24 and Claim 12 is drawn to 4 different underlined peptides represented in Figure 26. Given the "at least" language recited in the claims, it is clear that by factorial analysis, the 4 epitopes of claim 2 represent 24 different combinations, minus 1 group for the group included in Group 1, above. By factorial analysis Figure 22 is drawn to 5040 combinations, minus 1 group for the group

included in Group 1, above. By factorial analysis Figure 24 represents 479, 991,600 combinations. By factorial analysis Figure 26 represents 24 combinations. Thus, the claims are drawn to 479,996,686 Groups consisting of different combinations. Applicant is required to identify and elect a single group for examination. It is noted for Applicant's convenience that **this is not a requirement for an election of species**, but rather a requirement for the election of a specific group for examination.

Group 479,996,687, claims 16-18, 26 drawn to an antibody capable of distinguishing between porcine polypeptides and homologous polypeptides of a mammal.

Groups 479,996,688-479,996,714, claim 19 drawn to a method of monitoring an immune status of a mammalian recipient of a xenograft comprising contacting with an antibody and monitoring expression of a porcine polypeptide shown in Figures 22, 24, 26. It is noted that Figure 22 discloses 7 underlined polypeptides as well as an apparently complete polypeptide, Figure 24 discloses 12 underlined polypeptides as well as an apparently complete polypeptide, Figure 26 discloses 4 underlined polypeptides as well as an apparently complete polypeptide. Thus the claim is drawn to monitoring a total of 26 different polypeptides, each of which represents a distinct group. Applicant is required to identify and to elect a single group for examination. It is noted for Applicant's convenience that **this is not a requirement for an election of species**, but rather a requirement for the election of a specific group for examination.

Groups 479,996,715, claims 20-23 drawn to a method of treating a mammal prior to receiving a xenograft.

3. The inventions are distinct, each from the other because of the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

The inventions listed as Groups 1-479,996,715 do not relate to a single inventive concept for the following reasons:

Group 1, claims, 2-in-part drawn to CD40, 6, 7, 8, 9-in-part drawn to CD40, claim 10-in-part if amended to recite "B-cell epitope" rather than "B-cell", 14, 15, 24, 25 form a single general inventive concept because the claims are draw to a product and a process of using said product.

Groups 2-479,996,715 are not so linked to Group 1 as to relate to a single inventive concept because they are drawn to multiple products, and uses that are different from those recited in Group 1.

4. Because these inventions are distinct for the reasons given above restriction for examination purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella Ungar, Ph.D. whose telephone number is (703) 308-308-8362.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

Karen A. Canella, PhD
Patent Examiner
September 30, 2003